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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,284	06/17/2002	Jacqueline Marchand	DCLERC 1	9585

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EXAMINER

SMALL, ANDREA D SOUZA

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 09/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/049,284	Applicant(s) MARCHAND ET AL.	
	Examiner Andrea D Small	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-8 and 26-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-8 and 26-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 10-20 and 22-25 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

I. Preliminary Matters:

(a) Amendment filed 6/16/2003 has been received and entered into the file.

- claims 6-35 were pending.
- Claims 9, 21 and 35 have been cancelled; consequently, claims 6-8, 10-20 and 22-34 are pending.
- Claims 10-20 and 22-25 have been withdrawn from consideration as being drawn to non-elected inventions. 37 CFR 1.142(b).

II. Remarks:

(a) Restriction/Election:

The traversal of the restriction requirement has been withdrawn.

(b) Rejection under 35 USC 101:

Claim 21 has been cancelled, hence the rejection is moot and has been withdrawn.

(c) Rejection under 35 USC 112(2)

-Rejection of claim 21 has been withdrawn as it has been cancelled.

-Amendment to claim 6 has obviated the rejection of claims 6-9, therefore, the rejection has been withdrawn.

(d) Rejection under 35 USC 102(b):

Applicants have traversed the rejection by arguing that claims 35 and 6 are not anticipated by Koch, et al as the reference does not disclose the preparation of halogenated nitro aromatic compounds that are F18 labeled. Additionally, that the reference does not anticipate much less render obvious a process where compounds are per se from F18 labeled precursors.

The examiner respectfully disagrees. The reference does anticipate original claim 35 (now cancelled) and claim 6 and newly amended claim 31. The reference specifically teaches that depending on the ultimate compound required, the starting materials could be varied. The reference then goes on to describe the process in which these starting materials may be varied. The starting materials are as those described in cancelled claim 35, claim 6 and newly amended claim 31. The starting materials being 2-(2-nitro-imidazol-1-yl) acetic acid (the acetamide undergoes alkaline hydrolysis at the carbonyl group to yield an acid derivative) and then followed by the rapid addition of F18 labeled halogenated alkyl amine. See col. 11, lines 34-53.

With reference to the usage claims 26-30, where the method of preparing F18 labeled compounds as seen in claim 31, claims 26-30, the methods of preparing is anticipated, see discussion supra and the methods of using the compounds thus prepared are also known, these claims are still anticipated. See col. 7, lines 10-63 and claim 20.

Claims 32-34 have been amended to product by process claims and they still read on the products that are still anticipated by the reference in col. 6, lines 4-44, particularly lines 39-43, also see col. 14, lines 18-25, also see claims 14-18.

Thus, the rejections of claims 6-8 and 26-34 are maintained.

(e) Objections:

The objections to claim 7-9 and 21 are not withdrawn as they still depend from a later occurring claim.

The objections to claim 7-8 have been withdrawn in view of the amendments provided.

III. Maintained Rejections:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6-8 and 26-34 rejected under 35 U.S.C. 102(b) as being anticipated by Koch, et al (Us 5,540,908).

Applicant's claims relate to compounds of formula I, pharmaceutical compositions and methods of using the same.

(a) Claims 32-34 are anticipated by Koch, et al where R² is an alkyl substituted by halogen, the reference also teaches that in the preferred embodiment of the invention, the compound exists with a F18 isotope as instantly claimed. See col. 6, lines 4-44, particularly lines 39-43, also see col. 14, lines 18-25, also see claims 14-18.

(b) Claims 31 and 6 are also anticipated by the reference, see col. 11, lines 28-53 and lines 45-53.

(c) Claims 7-8 are anticipated by the teaching in col. 11, lines 34-45.

(d) Claims 26-30, drawn to the methods of use in detection of hypoxia are also anticipated by the reference in col. 7, lines 10-63 and claim 20.

Claims 7-8 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Instantly, claims 7-8 depend from a later occurring claim, claim 31.

IV. New Rejections/Objections:

- (a) Claim 6 is objected to under 37 CFR 1.75©, as being improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Instantly, claim 6 depends from cancelled claim 35.
- (b) Claims 10-20 and 22-25 are objected to as being drawn to non-elected inventions. 37 CFR 1.142(b).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

V. Contact Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrea D. Small, whose telephone number is (703) 305-0811. The examiner can normally be reached on Monday-Thursday from 8:30 AM - 7:00 PM.

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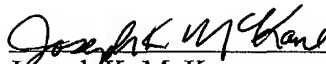
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial fax phone number for this Group is (703) 308-7921. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [Joseph.McKane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1234

Andrea D. Small, Esq.
September 10, 2003



Joseph K. McKane
Supervisory Patent Examiner
Art Unit 1626
Technology Center 1